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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/485,640	02/11/00	ODAKA	H 2477US0P

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EXAMINER	
JIANG,S	
ART UNIT	PAPER NUMBER
1617	5

DATE MAILED: 06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/485,640	Applicant(s) ODAKA ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

This application is a 371 of PCT/J98/00756.

This application claims the foreign priority under 35 U.S.C. 119(a)-(d). The copy of the certified copy in Paper No. 1 submitted with the application is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "TNF-α" in claims 1, 11 and 12 renders claims 1-12 indefinite. The expression "TNF-α" is not defined by the claims. Therefore, the scope of claims is indefinite as to the expression "TNF-α" encompassed thereby.

In order to expedite prosecution, claims 1-12 will be examined using the expression "Tumor Necrosis Factor -α" as "TNF-α" defined in line 7 on page 1 of the specification as has apparently been intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al. (A12, PTO-1449 submitted February 11, 2000).

Stevenson et al. teaches that three particular active agents, ciglitazone, troglitazone, and pioglitazone (5-[4-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-2,4-thiazolidinedion), within the instant claim, are anti-diabetic agents known useful in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in mammal by reducing of the elevated Tumor Necrosis Factor -α (TNF-α) mRNA levels in mammal. See Introduction on page 175, and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186. Therefore, to administer effective amount of ciglitazone, troglitazone, or pioglitazone to prevent a TNF-α mediated inflammatory disease in a mammal would be inherent in the method of the treatment disclosed by Stevenson et al. (see *Ex parte Novitski* 26 USPQ 2d 1389). Thus, Stevenson et al. anticipates the claimed invention.

Claims 1-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Szalkowski et al. (A10, PTO-1449 submitted February 11, 2000).

Szalkowski et al. teaches that three particular active agents, ciglitazone, pioglitazone, and CS-045 (troglitazone), within the instant claim, are anti-diabetic agents known useful in a composition and a method of the treatment of non-insulin-dependent

diabetes mellitus in animals by blocking the inhibitory effect of TNF-α on insulin-stimulated glucose uptake in mammals. See abstract and page 1474 and Figure 1 on page 1476. Therefore, to administer effective amount of ciglitazone or troglitazone or pioglitazone to prevent a TNF-α mediated inflammatory disease in a mammal would be inherent in the method of the treatment disclosed by Szalkowski et al. (see *Ex parte Novitski* 26 USPQ 2d 1389). Thus, Szalkowski et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al. (A12, PTO-1449 submitted February 11, 2000) and Szalkowski et al. (A10, PTO-1449 submitted February 11, 2000).

Stevenson et al. teaches that particular active agents herein such as ciglitazone, pioglitazone and troglitazone, within the instant claim, are anti-diabetic agents known useful in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in animals. Stevenson et al. also teaches that many analogues of clofibrate such as ciglitazone are known to be synthesized for a method of using in manufacture. See Introduction on page 175 and Figure 1 on page 176.

Szalkowski et al. teaches that particular active agents herein such as ciglitazone, pioglitazone, and CS-045 (troglitazone), within the instant claim, are anti-diabetic agents known useful in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in animals by blocking the inhibitory effect of TNF-α on insulin-stimulated glucose uptake in mammals. See abstract and page 1474 and Figure 1 on page 1476.

The prior art does not expressly disclose that the particular compound, (R)-(+)-5-[3-[4-[2-(2-furyl)-5-methyl-4-oxazolylmethoxy]-3-methoxyphenyl]propyl]-2,4-oxazolidinedion, is anti-diabetic agent useful in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in animals.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound herein in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in animals.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular compound herein in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in animals since the active compounds of the formula in the instant claim 1 are known to be useful in a composition and a method of use. This particular compound is one of compounds of the formula in claim 1 herein. Therefore, one of ordinary skill in the art would have found it obvious to employ this particular compound for the same purprose.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (6,133,293, PTO-892) and (6,172,089, PTO-892) in view of Stevenson et al. (A12, PTO-1449 submitted February 11, 2000).

Ikeda et al. discloses that active compounds in effective amounts, within the instant claim, are useful in a pharmaceutical composition and a method for prophylaxis or the treatment of diabetes in animals. See '293 col.2 – col.10, Working Examples 1-3, and claims 1-13; and '089 col.2 – col.10, Working Examples 1-3, and claims 1-7.

Ikeda et al. does not expressly disclose that active compounds herein are useful in a method for treating or preventing TNF-α mediated inflammatory disease in a mammal.

Stevenson et al. teaches that active compounds, within the instant claim, are anti-diabetic agents known useful in a composition and a method of the treatment of non-insulin-dependent diabetes mellitus in animals by reducing of the elevated TNF-α mRNA levels in a mammal. See Introduction on page 175 and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ active compounds herein are useful in a method for treating or preventing TNF-α mediated inflammatory disease in a mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ active compounds herein are useful in a method for treating or preventing TNF-α mediated inflammatory disease in a mammal since active compounds herein are known to be useful in a pharmaceutical composition and a

method of treating diabetes in a mammal. It is well known that insulin-resistant diabetes mellitus is associated with the elevated TNF-α mRNA levels in mammal. It is also well known that rheumatoid arthritis, an inflammatory disease, is associated with the production of TNF-α increase. Active agents herein are known to be useful in a method of treating insulin-resistant diabetes mellitus by reducing the elevated TNF-α mRNA levels in mammal based on the teaching of Stevenson et al. Therefore, one of ordinary skill in the art would have found it obvious to employ these compounds in a method for treating or preventing inflammatory disease caused by TNF-α increase in a mammal.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,965,584 in view of Stevenson et al. (A12, PTO-1449 submitted February 11, 2000).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent are drawn to a pharmaceutical composition and a method of treating diabetes in a mammal comprising active agents, within the instant claim. The claim of the instant application is drawn to active agents herein useful in a pharmaceutical composition and a method for treating or preventing TNF-α mediated inflammatory disease in a mammal. One having ordinary skill in the art at the time the invention was made would have been motivated to employ active compounds herein in a pharmaceutical composition and a method for treating or preventing TNF-α mediated inflammatory disease in a mammal since active compounds herein are known to be useful in a pharmaceutical composition and a method of treating diabetes in a mammal. It is well known that insulin-resistant diabetes mellitus is associated with the elevated TNF-α mRNA levels in mammal. It is also well known that rheumatoid arthritis, an inflammatory disease, is associated with the production of TNF-α increase. Active agents herein are known to be useful in a method of treating insulin-resistant diabetes mellitus by reducing the elevated TNF-α mRNA levels in mammal based on the teaching of Stevenson et al. Therefore, one of ordinary skill in the art would have found it obvious to employ these compounds in a method for treating or preventing inflammatory disease caused by TNF-α increase in a mammal.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
June 6, 2001

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